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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,605	11/09/2001	Dennis E. Hallahan	1242/21 PCT/US	8170
25297 7590 04/18/2005 JENKINS, WILSON & TAYLOR, P. A. 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			EXAMINER KETTER, JAMES S	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,605

Applicant(s)

HALLAHAN, DENNIS E.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 106-184 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 106-111, 113-150, 152-156, 158-169, 171 and 174-184 is/are rejected.
- 7) ☒ Claim(s) 112, 151, 157, 170, 172 and 173 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 112, 151, 157, 170, 172 and 173 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 106-111, 113-126, 132-144, 146-150, 152-156, 158-169, 171 and 174-184 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger et al. (A, newly cited).

The delay in finding and citing the newly found art is regretted.

The instant invention is drawn to a delivery vehicle which comprises a targeting agent and a pharmaceutically acceptable diluent or excipient, and more narrowly an active agent, wherein the targeting agent preferentially binds to a radiation inducible target in a target tissue. More narrowly, the targeting agent is recited as the gamma subunit of fibrinogen. The active agent is more narrowly recited as an imaging agent, more narrowly recited as a paramagnetic agent or a radioisotope, e.g., ⁹⁹Tc or ¹¹¹In, or as a toxin, more narrowly an anti-tumor drug, more narrowly a radiotherapeutic agent, e.g., ⁹⁹Tc or ¹¹¹In. The radiation inducible target bound is recited more narrowly as a cell adhesion molecule, more narrowly ICAM-1, E- or P-

selectin, or Beta3 intergrin. The targeting agent is more narrowly recited as being the same as a carrier, which is more narrowly recited as, among others, a liposome.

Unger et al teaches, e.g., at paragraph [0220], that the gamma subunit of fibrinogen may be used as the targeting ligand in the disclosed invention. At, e.g., [0060], it is taught that the bioactive agent of the invention may be, e.g., drugs or diagnostic agents. At the subsequent paragraph it is taught that the diagnostic agent may be a magnetic resonance imaging agent, i.e., a paramagnetic label, and that a lipid vesicle may be employed as well. At [0341], a paramagnetic agent is specifically taught. At [0360], ⁹⁹Tc and ¹¹¹In radioisotopes are taught as imaging agents. Such a radioisotope would inherently meet the limitations as therapeutic toxins, depending on the manner of use, e.g., dosage. Fibrinogen inherently targets preferentially to the cell adhesion molecules as enumerated, such being the basis of both the claimed invention and that of Unger et al.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 106-108, 113-137, 142-147 and 152 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record set forth in the previous Office Action, mailed 8 September 2004.

Applicant argues, at the paragraph bridging pages 15 and 16 of the amendment filed 8 February 2005, that there is a strong presumption of adequate written description as filed in an

application. Clearly, however, this is a point of guidance only, and where written description is determined not to be adequate, this presumption is no longer relevant. Further along, Applicant argues that the examples of radiation induced targets constitute a representative sample of such targets. However, given the unpredictable nature of biological systems, and the concomitant lack of knowledge of structure-function relationships for proteins, and that Applicant's assertion is unsupported with any facts beyond those in the specification, it is not at all apparent that the listing of target molecules in the specification would have been recognized by one of skill in the art as having been representative of the genus.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jsk
April 14, 2005



JAMES KETTER
PRIMARY EXAMINER